K111248

YTY INDUSTRY (MANJUNG) SDN. BHD.

(Company No : 380830-P)
Lot 1422-1424, Batu 10 Lekir, 32020 Sitiawan, Perak Darul Ridzuan, Malaysia.
Tel : 05-6792288 (Hunting Line), 6792443 & 6792445 Fax : 05-6791188

DEC - 1 2011

510 (K) SUMMARY SHEETS

1.0 **SMDA 510 (K) SUMMARY**

2.0 Submitter

YTY INDUSTRY (MANJUNG) SDN. BHD.,
Lot 1422-1424, Batu 10 Lekir
32020 Sitiawan, Perak,
Malaysia

Tel 605-6792288

Fax 605-6791188

Name of Contact Person 1. Mr. Roger Moh Ung Nang
2. Mr. Arivalagan

Date of Summary Prepared November 1, 2010

3.0 Name of Device

Trade Name: **Non-Sterile, Powder-Free Nitrile Examination Gloves (Original Blue, Cobalt Blue) Tested for use with Chemotherapy Drugs.**

Common Name: Synthetic Rubber Examination Gloves

Classification Name: Patient Examination Glove, Powder Free

4.0 Identification of The Legally Marketed Devices

The legally marketed device to which we claim substantial equivalence is **K101822, Blue Nitrile Examination Gloves, Tested for Use With Chemotherapy Drugs Labeling Claim, (Non-Sterile),** which is a Class 1 device with Product Codes **LZA/LZC.** The predicate device was approved Nov 19, 2010. Except for the color differences, and some different chemotherapy chemicals breakthrough testing times, we do claim this submission is essentially equivalent.

5.0 Description of The Device

Non-Sterile, Powder-Free Nitrile Examination Gloves (Original Blue, Cobalt Blue) Tested for use with Chemotherapy Drugs, meets all the current specifications listed under ASTM Specifications D6319-05 , Standard Specification for Nitrile Examination Gloves for Medical Application and D6978-05, Standard Practice for Assessment of Resistance to Permeation by Chemotherapy Drugs.

K111248

6.0 The Intended Use of Glove

A patient examination gloves is a disposable device intended for medical purpose that is worn on the examiner's hand or fingers to prevent contamination between patient and examiner. This device is for over-the counter use.

7.0 Summary of Performance Data:

Performance data of gloves based on ASTM D6319-10 and FDA 1000ML watertight test.

Test	**FDA 1000ml Water Leak Test**	Powder Free Nitrile Examination Gloves	
1. Watertight (1000ml)	Multiple Normal GI AQL = 2.5	Original Blue Pass	Cobalt Blue Pass
Test	ASTM D6319-10		
2. Length (mm) Size M L XL	Min 230 (chemo claim min 270) Min 230 (chemo claim min 270) -	273 - 278	276 - 278
3. Palm width (mm) Size M	95 ± 10	97 – 99	98 – 99
4. Thickness (mm) (Single Layer) Finger Palm	 Min 0.05 (chemo claim min0.10) Min 0.05 (chemo claim min0.10)	 0.15 – 0.21 0.11 – 0.12	 0.16 – 0.20 0.11 – 0.12
5. Physical Properties Before Aging Tensile Strength (MPa) Ultimate Elongation (%) After Aging Tensile Strength (MPa) Ultimate Elongation (%)	 Min 14 Min 500 Min 14 Min 400	 20.3 – 25.9 580 – 620 26.5 – 35.6 500 - 520	 19.6 – 25.3 560 – 580 25.0 – 28.4 460 - 520
6. Powder Content	Max 2.0mg/glove	0.34 mg/glove	0.39 mg/glove
7. Moisture Content	Max 2.0%	0.92%	0.84%

510 (k) Summary
Page 2 of 4 revised 10-20-2011
Joann Tucker

SUBSTANTIAL EQUIVALENCE COMPARISONS

TESTED PERFORMANCE DATA FOR BLUE YTY POWDER FREE NITRILE EXAM GLOVES WITH CHEMO DRUG LABELING CLAIMS			SGMP K101822 BLUE NITRILE CHEMO TESTED
ASTM D6319-05 NITRILE SPECIFICATION	ORIGINAL	COBALT	K101822
FDA 1000ML Water Tight AQL	2.5	2.5	2.5
Length (mm)	244-249	247-250	295
Width (mm)	97-99	98-99	95
Thickness (mm)			
Finger:	0.12 - 0.14	0.12 - 0.13	0.18 - 0.21
Palm:	0.06 - 0.07	0.07 - 0.08	0.16 - 0.19
Tensile Strength (Mpa)			
Before Aging	17.8 - 20.0	23/0 - 27.0	14
After Aging	21.3 - 23.6	30.2 - 34.6	14
Ultimate Elongation (%)			
Before Aging	680 - 720	660 - 680	500
After Aging	600 - 620	560 - 580	400
Finished Total Powder Level (mg/glove	0.48	0.22	<2.0
Biocompatibility Testing (CPTC)			
Pass Primary Skin Irritation in Rabbits	Yes	Yes	Yes
Pass Guinea Pig Maximization	Yes	Yes	Yes
CHEMOTHERAPY TESTING BY ARDL CHEMICAL ANALYTICAL SERVICES			
Minimum Breakthrough Detection Time in Minutes:			
Carboplatin, 10 mg/ml	>240	>240	Not tested
Carmustine (BCNU), 3.3 mg ml	1.84	1.82	0.49
Cisplatin, 1.0 mg/ml	>240	>240	>240
Cyclophosphamide (Cytoxan), 20.0 mg/ml	>240	>240	>240
Dacarbazine (DTIC), 10.0 mg/ml	>240	>240	>240
Doxorubicin Hydrochloride, 2.0 mg/ml	>240	>240	>240
Etoposide (Toposar), 20.0 mg/ml	>240	>240	>240
Fluorouracil, 50.0 mg/ml	>240	>240	>240
Ifosfamide, 50.0 mgs/ml	>240	>240	Not tested
Methotrexate, 25 mg/ml	>240	>240	>240
Mitomycin C, 0.5 mg/ml	>240	>240	Not tested
Mitoxantrone, 2 mg/ml	>240	>240	Not tested
Paclitaxel (Taxol), 6.0 mg/ml	>240	>240	>240
Thiotepa, 10.0 mg/ml	0.76	0.93	2.61
Vincristine Sulfate, 1.0 mg/ml	>240	>240	>240

WARNING: DO NOT USE WITH CARMUSTINE OR THIOTEPA is included as warnings on all three products (YTY and SGMP labeling claims)

8.0 The performance data of the glove as shown above meet the ASTM D6319-05 Standard and FDA's requirement.
Powder content is below 2 mg per glove which meet the FDA Requirements.

9.0 The Bio-compatibility Test consists of Primary Dermal Irritation Test and Guinea Pig Sensitization (Buehler) test. For both colors
The gloves pass the Bio-compatibility Test.

10.0 Conclusion

We conclude that the Non-Sterile, Powder-Free Nitrile Examination Gloves (Original Blue, Cobalt Blue) Tested for use with Chemotherapy Drugs does meet:

- ASTM D6319-05 Standard
- FDA pinhole requirements
- Are below the maximum Powder Residual Content as specified in ASTM D6319-05
- ASTM D5151 (which equates to the FDA Water Leak Test)
- ASTM D6978-05 (Chemotherapy Testing Standards)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

DEC - 1 2011

YTY Industry (Manjung) Sdn. Bhd.
C/O Ms. Janna P. Tucker
Consultant
Tucker & Associates
198 Avenue De La D'Emerald
Sparks, Nevada 89434

Re: K111248
Trade/Device Name: Non-Sterile, Powder Free Nitrile Examination Gloves (Original Blue, Cobalt Blue). Tested for Use with The Below Chemotherapy Drugs
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Gloves
Regulatory Class: I
Product Code: LZA, LZC
Dated: November 10, 2011
Received: November 21, 2011

Dear Ms. Tucker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices /ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem /default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices /ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

APPLICANT: YTY INDUSTRY (MANJUNG) SDN BHD

510(K) NUMBER: K111248

DEVICE NAME: Non-Sterile, Powder Free Nitrile Examination Gloves (Original Blue, Cobalt Blue). Tested for use with the below chemotherapy drugs.

INDICATIONS FOR USE:
A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or fingers to prevent contamination between patient an examiner.

Chemotherapy Drug Permeation (breakthrough detection time) in minutes.
The following chemicals have been tested with these gloves:

TESTED CHEMOTHERAPY DRUG	Original Blue Average Breakthrough Detection Time in Minutes	Original Blue Average Breakthrough Detection Time in Minutes
Carboplatin, 10 mg/ml	>240	>240
Carmustine (BCNU), 3.3 mg/ml)	** 1.84	** 1.82
Cisplatin, 1.0 mg/ml	>240	>240
Cyclophosphamide (Cytoxan), 20.0 mg/ml	>240	>240
Dacarbazine (DTIC), 10.0 mg/ml	>240	>240
Doxorubicin Hydrochloride, 2.0 mg/ml	>240	>240
Etoposide (Toposar) 20.0 mg/ml	>240	>240
Fluorouracil, 50.0 mg/ml	>240	>240
Ifosfamide, 50.0 mg/ml	>240	>240
Methotrexate, 25 mg/ml	>240	>240
Mitomycin C, 0.5 mg/ml	>240	>240
Mitoxantrone, 2 mg/ml	>240	>240
Paclitaxel (Taxol) 6.0 mg/ml	>240	>240
Thiotepa, 10.0 mg/ml	** 0.76	** 0.93
Vincristine Sulfate, 1.0 mg/ml	>240	>240

** Please note that Carmustine (BCNU)and Thiotepa have extremely low permeation times for both glove colors. These two chemicals are not recommended for use with either color of the gloves.

Prescription Use_____ **and/or** **Over-The-Counter** ✓
(Part 21 CFR 801.Subpart D **21 CFR 801.Subpart C**

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K111248